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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,370	01/23/2001	Jeffrey Browning	A054 US	2716

7590

05/20/2003

Niki Cox  
Biogen, Inc.  
14 Cambridge Center  
Cambridge, MA 02142

EXAMINER
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YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/20/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/767,370

Applicant(s)

BROWNING ET AL.

Examiner

Christopher H Yaen

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 12-15, 20-25 and 30-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-19 and 26-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. The amendment filed 2/21/2003 (paper no 16) is acknowledged and entered into the record. Accordingly, no claims have been added or canceled.
2. Claims 1-36 are pending, claims 1-7, 12-15, 20-25, 30-36 are withdrawn from further consideration as being drawn to a non-elected subject matter. Applicant is reminded to cancel claims drawn to non-elected invention(s).
3. Therefore, claims 8-15, 16-19, and 26-29 are examined on the record.

#### ***Information Disclosure Statement***

4. The Information Disclosure Statement filed 2/21/2003 (paper no. 17) is acknowledged and considered. A signed copy of the IDS is attached hereto.

#### ***Claim Rejections Withdrawn - 35 USC § 112, 2<sup>nd</sup> paragraph***

5. The rejection of claim 16 under 35 USC 112, 2<sup>nd</sup> for being indefinite in the recitation of the term "protein-Ig fusion" is withdrawn in view of the amendment to the claims.
6. The rejection of claims 8-11, 16-19, and 26-29 under 35 USC 112, 2<sup>nd</sup> paragraph for being indefinite in the recitation of the term "fusion" is withdrawn in view of the amendments to the claims.
7. The rejection of claims 10-11 and 18-19 under 35 USC 112, 2<sup>nd</sup> paragraph for being indefinite in the recitation of the term "fragment" is withdrawn in view of the cancellation of the claims.

Art Unit: 1642

8. The rejection of claims 8,16,26 and dependent claims thereof for being indefinite in the recitation of the term "about" is withdrawn in view of the arguments presented by the applicant.

***Claim Rejections Withdrawn - 35 USC § 112, 1<sup>st</sup> paragraph***

9. The rejection of claims 10,11,18, and 19 under 35 USC 112, 1<sup>st</sup> paragraph as lacking proper written description to the extent that it reads on "fragments," is withdrawn in view of the amendments to the claims.

***Claim Rejections Withdrawn - 35 USC § 101***

10. The rejection of claims 11, 19, and 29 under 35 USC 101 as lacking a patentable utility is withdrawn in view of the arguments presented by the applicant.

***Claim Rejections Maintained - 35 USC § 112, 2<sup>nd</sup> paragraph***

11. The rejection of claims 8,16, 26 and dependent claims thereof under 35 USC 112, 2<sup>nd</sup> paragraph for being indefinite in the recitation of the term "active" is maintained for the reasons of record. Applicant argues that the term is intended to mean a protein that is both functional and has high affinity. Applicant's arguments have been carefully considered but is not found persuasive because the term in itself does not only imply functionality or affinity but also the state of protein's role in a biological system.

Furthermore, it is a relative term from which no basis of comparison can be made.

12. The rejection of claims 28-29 under 35 USC 112, 2<sup>nd</sup> paragraph for being indefinite in the recitation of the term "fragment" is maintained for the reasons of record. Applicant states that the term has been deleted, thereby rendering the rejection moot. However, it is noted that both claims 28 and 29 still recite the term "fragment".

Art Unit: 1642

Applicant's arguments have been considered but is not found persuasive because one of skill in the art although would understand the meaning of the term in a general sense, would not know what those fragments are. Because those fragments have not been identified, one of skill in the art would find it difficult to understand the intended metes and bounds of the term.

13. The rejection of claims 8-11, 16-19, and 26-29 under 35 USC 112, 2<sup>nd</sup> paragraph for being indefinite in the recitation of the term "fusion" is maintained for the reasons of record. Applicant's amendment has not clarified what type of "fusion" is being claimed. Because the actual fusion being claimed is not clearly delineated the metes and bounds of the term cannot be determined.

***Claim Rejections Maintained - 35 USC § 112, 1<sup>st</sup> paragraph***

14. The rejection of claims 28 and 29 under 35 USC 112, 1<sup>st</sup> paragraph as lacking proper written description in reference to fragments, is maintained for the reasons of record. It is noted that applicant states that the term was removed from the claims thereby rendering the rejection made of record moot. However, the term remains within the scope of the claims and because no arguments have been presented to rebut the rejections made of record, this rejection is maintained.

***Claim Rejections Maintained - 35 USC § 102***

15. The rejection of claims 8-10 under 35 USC 102(b) as being anticipated by the art of record is maintained for the reasons of record. Applicant argues that the claims are not anticipated by the Crowe *et al* reference because the reference teaches the culturing of mammalian host cells for the production of a fusion protein. Applicant's

Art Unit: 1642

arguments have been carefully considered but are not found persuasive because the claims are drawn to a product, and regardless of how the product is made, the product is already disclosed in the art. The methodology claimed, is also found in the art and was presented in the Crowe *et al* reference as an example of how the product by process claimed is not patentable distinct over the art. The design of culturing the cell in a mammalian host is considered a design choice and does not render the claims free of the prior art because the product irregardless of how the product was made is still the same product.

### ***Conclusion***

16. No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1642

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen  
Art Unit 1642  
May 19, 2003

  
ALI R. SALIMI  
PRIMARY EXAMINER